REMARKS

Claims 1 and 12-19 are pending. Claims 1 and 18 have been amended. Support for the amended claims can be found throughout the specification and in the claims as originally filed. Upon entry of this amendment, claims 1 and 12-19 will be pending. No new matter enters by way of these amendments.

I. Re-Opening of Prosecution

Applicants acknowledge that prosecution has been re-opened by way of the Office Action mailed January 3, 2005 ("Office Action") and that new grounds of rejection are presented in the Office Action. In addition, the Examiner notes that "[t]o avoid abandonment of the application, appellant must exercise one of the following two options:" either "(1) file a reply under 37 CFR 1.111...; or (2) request reinstatement of the appeal." Office Action at page 2. Applicants hereby file the instant reply under 37 C.F.R. 1.111.

II. Rejections under 35 U.S.C. § 112, Second Paragraph

Claims 1, 18 and 19 stand rejected under 35 U.S.C. § 112, Second Paragraph as allegedly "being indefinite for failing to particularly point out and distinctly claim the subject matter applicant regards as the invention." Office Action at pages 2-3. Applicants respectfully disagree.

Applicants respectfully point out that the claims are to be read in light of the specification. *See in re Vogel*, 422 F.2d 438, 441, 164 U.S.P.Q. 619, 622 (C.C.P.A. 1970). The test for determining whether terms in a given claim are indefinite is whether

one skilled in the art would understand what is claimed. *Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd.,* 927 F.2d 1200, 18 U.S.P.Q.2d 1016 (Fed. Cir. 1991), *cert denied,* 112 S.Ct. 169 (1991). A person of ordinary skill in the art would understand the metes and bounds of the claims read in light of the disclosure of the specification.

Claims 1 and 18 are allegedly indefinite in the recitation of the phrase "fragment thereof" because it is allegedly not clear whether "the metes and bound said limitation as defined by the specification (page 36-38) are not clear." Office Action at page 3. Applicants respectfully disagree, however, in order to facilitate allowance, claims 1 and 18 have been amended to delete the phrase "or fragment thereof." Applicants respectfully request that the Examiner withdraw the indefiniteness rejection.

III. Rejection under 35 U.S.C. §101

Claims 1 and 12-19 stand rejected under 35 U.S.C. § 101 because the claimed invention allegedly is not supported by either a specific, substantial, and credible utility or a well-established utility. Applicants respectfully traverse this rejection.

Initially, the Examiner argues that "[t]he critical limitation of claims 1 and 12-19 is the elected polynucleotide SEQ ID NO: 5 that encodes a maize or a soybean adenine phosphoribosyl transferase." Office Action at page 4. Applicants note that the language "encodes a maize or soybean adenine phosphoribosyl transferase" is not contained in claims 12-19. Furthermore, as the cited language comes before the transition phrase "comprises," Applicants do not agree with the Examiner's allegation that such language is necessarily a "critical limitation" or a limitation of the claim at all.

The Examiner acknowledges that the specification discloses that "a sequence that is known in the prior art which has a stated sequence similarity to the claimed sequence." Office Action mailed January 3, 2005, at page 4. However, the Examiner argues that "the sequence of SEQ ID NO: 5 does not comprise the complete open reading frame that encodes for the complete adenine phosphoribosyl transferase protein." *Id.* at page 5. The Examiner also acknowledges that the specification describes multiple utilities for the present invention, including "in obtaining other nucleic acid molecules such as promoter sequences, identifying the presences or absence of polymorphisms, and determining expression profiling by probe hybridization." *Id.* at pages 5-6. However, the Examiner maintains that none of the utilities disclosed in the present application satisfy 35 U.S.C. § 101 because "[t]hese are non-specific uses that are applicable to nucleic acids in general and not particular or specific to the polynucleotide being claimed." *Id.* at page 6.

The "basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility...where specific benefit exists in currently available form." *Brenner v. Manson*, 383 U.S. 519, 534-35, 148 U.S.P.Q. 689, 695 (1966). As previously argued, Applicants have met this part of the bargain – the present specification discloses nucleic acid molecules which, in their current form, provide at least one specific benefit to the public, for example, use to identify a polymorphism in a population of plants. *See, e.g.* Specification at page 58, line 7 through page 66, line 2. This benefit is specific, not vague or unknown, and it is a "real world" or substantial benefit.

The "threshold for utility is not high: An invention is 'useful' under section 101 if it is capable of providing some identifiable benefit." *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1366, 51 U.S.P.Q.2d 1700, 1702 (Fed. Cir. 1999), *citing Brenner v. Manson*, 383 U.S. 519, 534 (1966). Furthermore, an invention need only provide one identifiable benefit to satisfy 35 U.S.C. § 101. *See Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 958, 220 U.S.P.Q. 592, 598 (Fed. Cir. 1983) ("when a properly claimed invention meets at least one stated objective, utility under section 101 is clearly shown").

The courts have expressed a test for utility that hinges on whether an invention provides an "identifiable benefit." *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1366, 51 U.S.P.Q.2d 1700, 1702 (Fed. Cir. 1999), *citing Brenner v. Manson*, 383 U.S. 519, 534 (1966). For analytical purposes, the requirement for an "identifiable benefit" may be broken into two prongs: (1) the invention must have a specific, *i.e.*, not vague or unknown benefit, *In re Brana*, 51 F.3d 1560, 1565, 34 U.S.P.Q.2d 1436, 1440 (Fed. Cir. 1995); and (2) the invention must provide a real world, *i.e.*, practical or "substantial" benefit. *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1563, 39 U.S.P.Q.2d 1895, 1899 (Fed. Cir. 1996). A corollary to this test for utility is that the invention must not be "totally incapable of achieving a useful result," *i.e.*, the utility must not be incredible or unbelievable. *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571, 24 U.S.P.Q.2d 1401, 1412 (Fed. Cir. 1992).

The present specification discloses several uses for the claimed nucleic acid molecules, including use as nucleic acid molecule markers and probes (*see, e.g.*, specification at page 45, line 1 through page 48, line 19); to identify and obtain nucleic

acid homologues (*see, e.g.,* specification at page 55, line 15 through page 57, line 2); in microarrays as gene-specific targets (*see, e.g.,* specification at page 76, line 14 through page 78, line 3); to identify the presence or absence of a polymorphism (*see, e.g.,* specification at page 58, line 7 through page 66, line 2); use to transform plants (*see, e.g.,* specification at page 82, line 16 through page 100, line 18); to determine the level or pattern of expression of a protein or mRNA associated with that nucleic acid molecule (*see, e.g.,* specification at page 71, line 14 through page 76, line 6); and use to overexpress or suppress a desired protein (*see, e.g.,* specification at page 101, line 7 through page 103, line 22).

The Examiner has acknowledged that the nucleic acids of the present invention may be used as probes, to detect the presence or absence of polymorphisms, and in expression studies, however the Examiner maintains that these utilities are not "useful" because they are "applicable to nucleic acids in general and not particular or specific to the polynucleotide being claimed." Office Action at page 6. The Examiner admits that SEQ ID NO: 5 encodes at least a fragment of an adenine phosphoribosyl transferase protein. However, the Examiner alleges that the specification "does not disclose that SEQ ID NO: 5 encodes the complete adenine phosphoribosyl transferase protein." Office Action at page 5.

The Examiner's assertions are not correct. Initially, the Examiner appears to be arguing that the asserted utilities are legally insufficient simply because other molecules can be used for the same purpose. Applicants maintain that that position is wrong as a matter of law – there is no requirement of exclusive utility in the patent law. *See Carl*

Zeiss Stiftung v. Renishaw PLC, 945 F.2d 1173, 1180, 20 U.S.P.Q.2d 1094, 1100 (Fed. Cir. 1991) ("An invention need not be the best or the only way to accomplish a certain result..."). Such an argument would imply that a new golf club has no legal utility because other golf clubs can be used for the same purpose, *i.e.*, hitting golf balls. That position must be rejected as it requires reading "into the patent laws limitations and conditions which the legislature has not expressed," a practice condemned by the Supreme Court. *See Diamond v. Chakrabarty*, 447 U.S. 303, 308, 206 U.S.P.Q. 193, 196 (1980), *quoting United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 199, 17 U.S.P.Q. 154, 162 (1933).

Furthermore, the specification clearly asserts that the nucleic acid molecules of the present invention encode maize or soybean adenine phosphoribosyl transferase proteins or fragments thereof. *See, e.g.,* specification at page 19, lines 2-5, page 206, line 4 through page 207, line 6 (Example 3), Table A and the sequence listing. The specification also explains the interrelationship of the enzymes involved in the cytokinin pathway, including adenine phosphoribosyl transferase (*see, e.g.,* specification at page 5, line 3 through page 9, line 19). In addition, the specification also discloses the methods used to analyze each of the claimed nucleic acid molecules and its association with the cytokinin pathway. *See, e.g.,* specification at page 5, line 3 through page 9, line 19 and Table A. One of ordinary skill in the art would recognize that the claimed nucleic acid molecules have utility, for example, to identify markers and isolate promoters in the cytokinin pathway of maize or soybean plants upon reading the present specification.

These utilities are immediately apparent for the claimed nucleic acid molecules without further research.

The Examiner maintains that the claimed nucleic acid molecules lack utility apparently because "the instant application does not disclose that SEQ ID NO: 5 encodes for the complete adenine phosphoribosyl transferase protein. *See* Office Action at page 5. However, as stated above, one of ordinary skill on the art would clearly be able to ascertain these elements based on Applicants' disclosure (*see, e.g.,* specification at page 5, line 3 through page 9, line 19 and page 206, line 4 through page 207, line 6 (Example 3), and Table A) and tools available to practitioners in the art, *e.g.,* BLASTX. Moreover, the specification discloses that the nucleic acid molecules of the present invention encode adenine phosphoribosyl transferase proteins or fragments thereof. Therefore, a complete ORF is not necessary for every claimed nucleic acid molecule. Furthermore, a complete ORF is not necessary to use the claimed nucleic acid molecules for the disclosed utilities, *i.e.,* as probes, to detect the presence or absence of polymorphisms, and in expression studies, all of which the Examiner acknowledges have been asserted in the specification.

The Examiner has not provided any support for the proposition that the claimed nucleic acid molecules would not work for the recited utilities; or that one skilled in the art would doubt that the claimed nucleic acid molecules would work for the utilities disclosed in the present specification. Applicants have thus provided sufficient evidence to lead a person of ordinary skill in the art to conclude that the asserted utilities are more likely than not true.

Applicants have disclosed several specific, substantial and credible utilities for the claimed nucleic acid molecules. Any one of these utilities is enough to satisfy the requirements of 35 U.S.C. § 101. Because Applicants need only establish a single utility to satisfy 35 U.S.C. § 101, and have done so in the present case, the rejection under Section 101 is incorrect. Reconsideration and withdrawal of this rejection are respectfully requested.

IV. Rejection under 35 U.S.C. § 112, first paragraph, Enablement

Claims 1 and 12-19 stand rejected under 35 U.S.C. § 112, first paragraph as not enabled because the claimed invention allegedly lacks utility. Office Action at page 5. Applicants respectfully traverse this rejection and contend that this rejection has been overcome by the arguments set forth above regarding utility. Thus, the enablement rejection under 35 U.S.C. § 112, first paragraph is improper. Applicants respectfully request reconsideration and withdrawal of this ground of rejection.

Applicants' acknowledge and thank the Examiner for indicating that "the lack of enablement rejection directed to claims 1, 18, and 19 in the previous Office Action, mailed May 05, 2003 (pages 3-5), has been withdrawn." Office Action at page 7.

V. Rejection under 35 U.S.C. § 112, first paragraph, Written Description

Claims 1 and 12-19 are again rejected under 35 U.S.C. § 112, first paragraph because the claimed subject matter allegedly was "not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s),

at the time the application was filed, had possession of the claimed invention." Office Action at page 8. Applicants respectfully traverse this rejection.

The Examiner, acknowledging that the "specification discloses the nucleic acid sequence as depicted by SEQ ID NO: 5 encoding fragments of adenine phosphoribosyl transferase." does not dispute that Applicants had possession of and have adequately described SEQ ID NO: 5. Office Action at page 8. However, the Examiner argues that the "[w]ith the exception of SEQ ID NO: 5 and the encoding fragments of adenine phosphoribosyl transferase, the sequences as encompassed by the full breadth of claims 1 and 12-19 do not meet the written description provision of 35 USC 112, first paragraph." *Id.* At page 8.

One of the Examiner's bases for this rejection appears to be that the rejected claims recite open claim language (comprising). *Id.* at pages 8-9. Such an argument conflicts with existing patent jurisprudence. It is well-established law that use of the transitional term "comprising" leaves the claims "open for the inclusion of unspecified ingredients even in major amounts." *Ex parte Davis*, 80 U.S.P.Q. 448, 450 (B.P.A.I. 1948). *Accord PPG Indus. v. Guardian Indus.*, 156 F.3d 1351, 1354, 48 U.S.P.Q.2d 1351, 1353-54 (Fed. Cir. 1998); *Moleculon Research Corp. v. CBS*, 793 F.2d 1261, 1271, 229 U.S.P.Q. 805, 812 (Fed. Cir. 1986). The very nature of "unspecified ingredients" is that they are <u>not</u> specified or described. The Examiner attempts to turn the legal meaning of "comprising" on its head by requiring Applicants to describe hypothetical claim elements. Applicants maintain that the claims as amended recite the required nucleic acid sequences, define the enzyme or fragment thereof encoded by the sequences, and recite

hybridization parameters and percent sequence identity. Applicants have described the claimed invention.

Applicants reiterate that the purpose of the written description requirement is to ensure that the inventors had possession of the claimed subject matter, *i.e.*, to ensure that the inventors actually invented what is claimed. *Gentry Gallery Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479, 45 U.S.P.Q.2d 1498, 1503 (Fed. Cir. 1998); *Lockwood v. American Airlines*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997); *In re Alton*, 76 F.3d 1168, 1172, 37 U.S.P.Q.2d 1578, 1581 (Fed. Cir. 1996). If a person of ordinary skill in the art would, after reading the specification, understand that the inventors had possession of the claimed invention, even if not every nuance, then the written description has been met. *In re Alton*, 76 F.3d at 1175, 37 U.S.P.Q.2d at 1584. A person of ordinary skill in the art would, after reading the present specification, understand that Applicants had possession of SEQ ID NO: 5, complements and variations thereof, sequences that hybridize to the claimed nucleic acid molecules under the recited conditions, as well as the enzymes, or fragments thereof, they encode. Applicants have indeed demonstrated possession of the claimed invention.

For example, the specification describes gene sequences, corresponding sequences from other species, mutated sequences, SNPs, polymorphic sequences, promoter sequences, exogenous sequences, and so forth (*see, e.g.,* specification at page 40, line 12 through page 42, line 4; page 45, line 1 through page 48, line 19; page 57, line 2 through page 58, line 6; and page 58, line 7 through page 66, line 2). The specification also describes appropriate hybridization conditions (*see, e.g.,* specification at 38, line 14

through page 39, line 8); nucleic acid molecules comprising nucleic acid sequences having conservative variations or encoding amino acid sequences having conservative substitutions (*see, e.g.,* specification at page 42, line 12 through page 43, line 21); fusion protein or peptide molecules or fragments thereof encoded by the nucleic acid molecules of the present invention (*see, e.g.,* specification at page 50, lines 8-19); plant homologue proteins (*see, e.g.,* specification at page 50, line 20 through page 51, line 10); site directed mutagenesis of the claimed nucleic acid molecules (*see, e.g.,* specification at page 78, line 4 through page 80, line 11); vectors comprising the claimed nucleic acid molecules and methods of transforming plants (*see, e.g.,* specification 82, line 17 through page 100, line 18); and construction of cDNA libraries using the claimed nucleic acid molecules (*see, e.g.,* specification at page 142, line 6 through page 206, line 3 (Examples 1-2)).

Thus, Applicants respectfully disagree with the Examiner's contention that despite the numerous variations of the claimed nucleic acid molecules described in the present specification, "with the exception of SEQ ID NO: 5 and the encoding fragments of adenine phosphoribosyl transferase, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides". Office Action at page 9. The Examiner appears to assert that each nucleic acid molecule within a claimed genus must be described by its complete structure. This assertion is unfounded. The test, promulgated by the Federal Circuit, stipulates that where a genus of nucleic acids may be described by a structural feature that distinguishes members of the claimed genus from non-members of the claimed genus, written description is satisfied. *See Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568-69, 43 U.S.P.Q.2d

1398, 1406 (Fed. Cir. 1997). In the present case, Applicants have satisfied that test for written description by providing a structural feature, namely nucleic acid molecules that distinguish members of the claimed genera from non-members.

Applicants maintain that they have provided a representative number of detailed chemical structures, i.e., the nucleic acid sequence of SEQ ID NO: 5, and their complements, as well as variants thereof. The common structural feature (the nucleotide sequence of SEQ ID NO: 5 and complements and variations thereof) is shared by every nucleic acid molecule in the claimed genera, and this feature distinguishes members of the claimed genera from non-members. For example, if a nucleic acid molecule such as an mRNA contains the nucleotide sequence of SEQ ID NO: 5, then it is a member of the claimed genus of nucleic acid molecules comprising a nucleic acid sequence of SEQ ID NO: 5.[1] If a nucleic acid molecule does not contain SEQ ID NO: 5, or complement or variant thereof, then it is not a member of that claimed genus. The presence of other nucleotides at either end of the recited sequence will not interfere with the recognition of a claimed nucleic acid molecule as such – it either contains the nucleotides of SEQ ID NO: 5 or it does not. Accordingly, the standard elucidated in *Lilly* for the written description requirement has been met.

Furthermore, nucleic acid molecules within the scope of the instant claims are also readily identifiable as they either encode a maize or soybean adenine phosphoribosyl

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[1] The same argument applies with equal force to every genus of the claimed nucleic acid molecules. For example, if a nucleic acid molecule such as an mRNA comprises a nucleic acid sequence that shares 90 % sequence identity with the nucleotide sequence of SEQ ID NO: 5, then it is a member of the claimed genus of nucleic acid molecules comprising a nucleic acid sequence having between 90% and 100% sequence identity with SEQ ID NO: 5. *See, e.g.,* claim 14.

transferase proteins or they do not. Claim 1 is directed to "substantially purified nucleic acid molecules that encode a maize or soybean" adenine phosphoribosyl transferase protein. Applicants respectfully maintain that the present specification complies with the written description requirement by describing nucleic acid sequences that encode maize or soybean adenine phosphoribosyl transferase protein. *See, e.g.*, Table A. Descriptions of complete ORFs are not required to comply with the written description requirement.

The fundamental factual inquiry for satisfying the written description requirement is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, that applicants were in possession of the invention as now claimed. See, *e.g.*, *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 U.S.P.Q.2d 1111, 1117 (Fed. Cir. 1991). An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997), M.P.E.P. § 2163.02. Moreover, the Examiner has failed to provide reasons why a person skilled in the art at the time the application was filed would not have recognized that Applicants were in possession of the invention as claimed in view of the disclosure of the application as filed. "A general allegation of 'unpredictability in the art' is not a sufficient reason to support a rejection for lack of adequate written description." MPEP § 2163 at 2100-170.

The Examiner has offered no evidence to demonstrate, in light of Applicants' disclosure, why one of ordinary skill in the art would reasonably doubt that the invention encompassed by Applicants' has not been adequately described in the present disclosure. As such, the Examiner has not met the burden to impose a written description rejection.

Based on the foregoing, Applicants respectfully submit that the currently pending claims are supported by an adequate written description pursuant to the requirements of 35 U.S.C. § 112. As such, reconsideration and withdrawal of the outstanding written description rejection are respectfully requested.

VII. Rejection under 35 U.S.C. § 102

Claims 1 and 12-19 are newly rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Moffat *et al.* (Plant Molecular Biology, v 18, pp 653-662, 1992). Office Action at page 12. According to the Examiner, "Moffat et al. discloses a complete cDNA for adenine phosphoribosyltransferase from *Arabidopsis thaliana*." *Id.* The Examiner further argues that the reference "discloses the adenine phosphoribosyltransferase comprising a fragment described by the amino acid sequence DP wherein a nucleotide sequence (GATCCC, positions 39-44) complements a nucleic acid sequence at 211-216 positions of SEQ ID NO: 5 (page 658) as in instant claims 1 and 18." *Id.*

"It is axiomatic that for prior art to anticipate under § 102 it has to meet every element of the claimed invention." *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 231 U.S.P.Q. 81 (Fed. Cir. 1986). Further, "an anticipation rejection requires a showing that each limitation of a claim must be found in a single reference, practice, or device." *In re Donohue*, 766 F.2d 531, 226 U.S.P.Q. 619 (Fed. Cir. 1985). The Examiner has applied an untenable interpretation of the claims to cover small fragments of the claimed sequence. Although Applicants disagree with the rejection, to facilitate prosecution, claims 1 and 18 have been amended to remove the phrase "or fragment

thereof." Whatever Moffat, *et al.* teaches, it does not disclose SEQ ID NO: 5 in its entirety. Nor does it disclose a nucleic acid molecule having between 90% and 100% identity with a nucleic acid molecule of SEQ ID NO: 5 or complete complement thereof. Absent a teaching of each and every element of the claim, *e.g.*, SEQ ID NO: 5, the reference cited by the Examiner does not anticipate claims 1 or 12-19 and the rejection should be withdrawn.

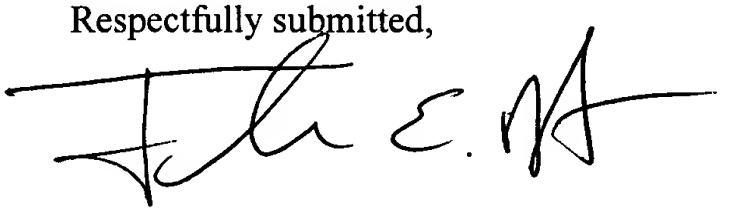
Claims 1 and 12-19 stand similarly rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by the Sigma Catalog (1990), product numbers 0 4628 ($d(pA)_6$) and 0 4378 ($d(pA)_4$). Office Action at page 13-14.

As argued above, the Examiner has again applied an untenable interpretation of the claims to cover small fragments of the claimed sequence. Although Applicants disagree, to facilitate prosecution, claims 1 and 18 have been amended to remove the phrase "or fragment thereof." Whatever the Sigma Catalog (1990) teaches, it does not disclose SEQ ID NO: 5 in its entirety. Nor does it disclose a nucleic acid molecule having between 90% and 100% identity with a nucleic acid molecule of SEQ ID NO: 5 or complete complement thereof. Absent a teaching of each and every element of the claim, *e.g.*, SEQ ID NO: 5, the Sigma Catalog cited by the Examiner does not anticipate claims 1 or 12-19 and the rejection should be withdrawn.

Conclusion

In view of the foregoing remarks, Applicants respectfully submit that the present application is now in condition for allowance, and notice of such is respectfully requested. The Examiner is encouraged to contact the undersigned should any additional information be necessary for allowance.

Respectfully submitted,



Thomas E. Holsten (Reg. No. 46,098)
David R. Marsh (Reg. No. 41,408)

Date: July 18, 2005 (Monday)

ARNOLD & PORTER LLP
Attn: IP Docketing
555 Twelfth Street, N.W.
Washington, D.C. 20004-1206
(202) 942-5000 telephone
(202) 942-5999 facsimile